K131937
Page 1 of 3

GE Healthcare
510(k) Premarket Notification Submission

510(k) Summary

In accordance with 21 CFR 807.92 the following summary of information is provided:

Date:	June 26, 2013
Submitter:	GE Healthcare [GE Healthcare Austria GmbH & Co OG] Tiefenbach 15 Zipf, Austria 4871
Primary Contact Person:	Bryan Behn Regulatory Affairs Manager GE Healthcare T:(414)721-4214 F:(414)918-8275
Secondary Contact Person:	Thomas Reisenberger Regulatory Affairs Specialist GE Healthcare Austria GmbH & Co OG T:(++43)7682-3800-332 F:(++43)7682 3800-47
Device: Trade Name:	Voluson i/e Diagnostic Ultrasound System
Common/Usual Name:	Voluson i/e
Classification Names:	Class II
Product Code:	Ultrasonic Pulsed Doppler Imaging System, 21CFR 892.1550 90-IYN Ultrasonic Pulsed Echo Imaging System, 21CFR 892.1560, 90-IYO Diagnostic Ultrasound Transducer, 21 CFR 892.1570, 90-ITX
Predicate Device(s):	K053435 Voluson i Diagnostic Ultrasound System K122327 Voluson E6/E8 E8 Expert/E10 Diagnostic Ultrasound System K120741 Voluson S6/S8 Diagnostic Ultrasound System K122387 Voluson P6/P8 Diagnostic Ultrasound System
Device Description:	The Voluson i/e consists of a portable, notebook type console with integrated keyboard controls and color LCD display. It supports a variety of. It utilizes a variety of linear, curved linear, transducers including mechanical scanning transducers supporting all standard acquisition modes (B, M, PWD, Color, Color M and Amplitude Doppler modes, Harmonic Imaging and Coded Pulse). The Voluson i/e also utilizes motor driven transducers and image processing software that are specialized for 3D/4D volume imaging. It provides high performance ultrasound imaging and analysis and has comprehensive networking and DICOM capability.

SEP 24 2013

Device Modification: Additional probes and software features cleared on the predicate devices have been added.

Addition of transducers – IC5-9W-RS (similar to IC5-9-D cleared on Voluson E Series K122327), RAB2-6-RS (Cleared on Voluson P6/P8 K122387), 8C-RS (Cleared on Voluson S6/S8 K120741). Transducers added via Appendix E of "Information for Manufacturers Seeking Marketing Clearance of Diagnostic Ultrasound Systems and Transducers", issued September 9, 2008" 9L-RS, RAB4-8-RS, RNA5-9-RS and RIC5-9W-RS, AB2-7-RS and SP10-16-RS.

Software improvements migrated from predicate K122327:

SRI (Speckle Reduction Imaging), XTD View (Extended View) and VCI (Volume Contrast Imaging), 4D-biopsy, STIC (Spatial Temporal Image Correlation) HD-Flow (High Density Flow), HD- Zoom (High Density Zoom), Volume Cine, Sono VCAD, Sono AVC, SonoNT and SonoRenderStart

Intended Use: The device is a general purpose ultrasound system. Specific clinical applications remain the same as previously cleared: Fetal/OB; Abdominal (including GYN, pelvic and infertility monitoring/follicle development); Pediatric; Small Organ (breast, testes, thyroid etc.); Cardiac (adult and pediatric); Musculo-skeletal Conventional and Superficial; Peripheral Vascular; Transvaginal; Transrectal

Technology: The Voluson i/e employs the same fundamental scientific technology as its predicate devices.

Determination of Substantial Equivalence: Summary of Non-Clinical Tests:

The device has been evaluated for acoustic output, biocompatibility, cleaning and disinfection effectiveness as well as thermal, electrical, electromagnetic, and mechanical safety, and has been found to conform with applicable medical device safety standards. The Voluson i/e and its applications comply with voluntary standards:

1. AAMI/ANSI ES60601-1, Medical Electrical Equipment – Part 1: General Requirements for Safety
2. IEC60601-1-2, Medical Electrical Equipment – Part 1-2:General Requirements for Safety – Collateral

Standard: Electromagnetic Compatibility Requirements and Tests

3. IEC60601-2-37, Medical Electrical Equipment – Part 2-37:Particular Requirements for the Safety of Ultrasonic Medical Diagnostic and Monitoring Equipment
4. NEMA UD 3, Standard for Real Time Display of Thermal and Mechanical Acoustic Output Indices on Diagnostic Ultrasound Equipment
5. ISO10993-1, Biological Evaluation of Medical Devices- Part 1: Evaluation and Testing- Third Edition
6. NEMA UD 2, Acoustic Output Measurement Standard for Diagnostic Ultrasound Equipment
7. ISO14971, Application of risk management to medical devices
8. NEMA, Digital Imaging and Communications in Medicine (DICOM) Set. (Radiology)

The following quality assurance measures were applied to the development of the system:

- Risk Analysis
- Requirements Reviews
- Design Reviews
- Testing on unit level (Module verification)
- Integration testing (System verification)
- Final Acceptance Testing (Validation)
- Performance testing (Verification)
- Safety testing (Verification)

Transducer materials and other patient contact materials are biocompatible.

Summary of Clinical Tests:

The subject of this premarket submission, Voluson i/e, did not require clinical studies to support substantial equivalence.

Conclusion: GE Healthcare considers the Voluson i/e to be as safe, as effective, and performance is substantially equivalent to the predicate device(s).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

September 24, 2013

GE Healthcare
% Mr. Bryan Behn
Regulatory Affairs Manager
9900 W. Innovation Drive
WAUWATOSA WI 53226

Re: K131937
Trade/Device Name: Voluson i/e
Regulation Number: 21 CFR 892.1550
Regulation Name: Ultrasonic pulsed doppler imaging system
Regulatory Class: II
Product Code: IYN, IYO, ITX
Dated: June 26, 2013
Received: June 27, 2013

Dear Mr. Behn:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

This determination of substantial equivalence applies to the following transducers intended for use with the Voluson i/e, as described in your premarket notification:

Transducer Model Number

RAB2-5-RS	RAB4-8-RS
RIC5-9-RS	RNA5-9-RS
RSP6-16-RS	AB2-7-RS
E8C-RS	9L-RS
4C-RS	SP10-16-RS
12L-RS	RAB2-6-RS
RIC5-9W-RS	8C-RS
IC5-9W-RS	

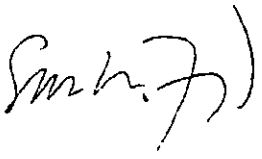
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,



for

Janine M. Morris
Director, Division of Radiological Health
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

510(k) Number (if known): K131937

Device Name: Voluson i/e Diagnostic Ultrasound System

Indications for Use:

The device is a general purpose ultrasound system.
Specific clinical applications include: Fetal/OB; Abdominal (including GYN, pelvic and infertility monitoring/follicle development); Pediatric; Small Organ (breast, testes, thyroid etc.); Cardiac (adult and pediatric); Musculo-skeletal Conventional and Superficial; Peripheral Vascular; Transvaginal; Transrectal

Prescription Use_X___ AND/OR Over-The-Counter Use_NA_
(Part 21 CFR 801 Subpart D) (Part 21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of *In Vitro* Diagnostics and Radiological Health (OIR)

Indications for Use Forms

The following forms represent indications with clinical applications and exam types along with the modes of operation for the Voluson i/e system and for all of its probe/mode combinations. Combinations identified by "N" are new while "P" represents those previously cleared with the unmodified Voluson i/e, P* indicates those added in this submission, but have clearance for the same modes and applications on another GE Ultrasound System. In a similar manner, "E" represents combinations added to the unmodified Voluson i/e via Appendix E of the FDA Ultrasound Guidance. This modification did not alter the previously cleared system level indications or clinical applications.

Diagnostic Ultrasound Indications for Use Form

GE Voluson i/e Ultrasound System

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application *Anatomy/Region of Interest*	Mode of Operation										
	B	M	PW Doppler	CW Doppler	Color Doppler	Color M Doppler	Power Doppler	Combined Modes	Harmonic Imaging	Coded Pulse	Other [Notes]
Ophthalmic											
Fetal / Obstetrics[7]	P	P	P		P	P	P	P	P	P	[5,6]
Abdominal[1]	P	P	P	P	P	P	P	P	P	P	[5,6]
Pediatric	P	P	P		P	P	P	P	P	P	[5,6]
Small Organ[2]	P	P	P		P	P	P	P	P	P	[5,6]
Neonatal Cephalic											
Adult Cephalic											
Cardiac[3]	P	P	P	P	P	P	P	P	P	P	[5]
Peripheral Vascular	P	P	P		P	P	P	P	P	P	[5,6]
Musculo-skeletal Conventional	P	P	P		P	P	P	P	P	P	[5,6]
Musculo-skeletal Superficial	P	P	P		P	P	P	P	P	P	[5,6]
Other											
Exam Type, Means of Access											
Transesophageal											
Transrectal[8]	P	P	P		P	P	P	P	P	P	[5,6]
Transvaginal	P	P	P		P	P	P	P	P	P	[5,6]
Transuretheral											
Intraoperative											
Intraoperative Neurological											
Intravascular											
Laparoscopic											

N = new indication; P = previously cleared by FDA; E = added under Appendix E

Notes: [1] Abdominal includes renal, GYN/Pelvic, Urology
[2] Small organ includes breast, testes, thyroid, salivary gland, lymph nodes, pediatric and neonatal patients
[3] Cardiac is Adult and Pediatric.
[5] 3D/4D imaging Mode
[6] Includes imaging of guidance of biopsy (2D/3D/4D)
[7] Includes infertility monitoring of follicle development
[8] Includes urology/prostate
[*] Combined modes are B/M, B/Color M, B/PWD or CWD, B/Color/PWD or CWD, B/Power/PWD.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostics and Radiological Health (OIR)

Prescription User (Per 21 CFR 801.109)

Diagnostic Ultrasound Indications for Use Form

GE Voluson i/e with RAB2-5-RS Transducer

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application *Anatomy/Region of Interest*	Mode of Operation										
	B	M	PW Doppler	CW Doppler	Color Doppler	Color M Doppler	Power Doppler	Combined Modes*	Harmonic Imaging	Coded Pulse	Other (Notes)
Ophthalmic											
Fetal / Obstetrics[7]	P	P	P		P	P	P	P	P	P	[5,6]
Abdominal[1]	P	P	P		P	P	P	P	P	P	[5,6]
Pediatric											
Small Organ[2]											
Neonatal Cephalic											
Adult Cephalic											
Cardiac[3]											
Peripheral Vascular											
Musculo-skeletal Conventional	P	P	P		P	P	P	P	P	P	[5,6]
Musculo-skeletal Superficial											
Other											
Exam Type, Means of Access											
Transesophageal											
Transrectal[8]											
Transvaginal											
Transuretheral											
Intraoperative											
Intraoperative Neurological											
Intravascular											
Laparoscopic											

N = new indication; P = previously cleared by FDA; E = added under Appendix E

Notes: [1] Abdominal includes renal, GYN/Pelvic, Urology
[2] Small organ includes breast, testes, thyroid, salivary gland, lymph nodes, pediatric and neonatal patients
[3] Cardiac is Adult and Pediatric.
[5] 3D/4D Imaging Mode
[6] Includes imaging of guidance of biopsy (2D/3D/4D)
[7] Includes infertility monitoring of follicle development
[8] Includes urology/prostate
[*] Combined modes are B/M, B/Color M, B/PWD or CWD, B/Color/PWD or CWD, B/Power/PWD.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostics and Radiological Health (OIR)

Prescription User (Per 21 CFR 801.109)

Diagnostic Ultrasound Indications for Use Form

GE Voluson i/e with RIC5-9-RS Transducer

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application *Anatomy/Region of Interest*	Mode of Operation										
	B	M	PW Doppler	CW Doppler	Color Doppler	Color M Doppler	Power Doppler	Combined Modes	Harmonic Imaging	Coded Pulse	Other (Notes)
Ophthalmic											
Fetal / Obstetrics[7]	P	P	P		P	P	P	P	P	P	[5,6]
Abdominal[1]											
Pediatric											
Small Organ[2]											
Neonatal Cephalic											
Adult Cephalic											
Cardiac[3]											
Peripheral Vascular											
Musculo-skeletal Conventional											
Musculo-skeletal Superficial											
Other											
Exam Type, Means of Access											
Transesophageal											
Transrectal[6]	P	P	P		P	P	P	P	P	P	[5,6]
Transvaginal	P	P	P		P	P	P	P	P	P	[5,6]
Transuretheral											
Intraoperative											
Intraoperative Neurological											
Intravascular											
Laparoscopic											

N = new indication; P = previously cleared by FDA; E = added under Appendix E

Notes: [1] Abdominal includes renal, GYN/Pelvic, Urology
[2] Small organ includes breast, testes, thyroid, salivary gland, lymph nodes, pediatric and neonatal patients
[3] Cardiac is Adult and Pediatric.
[5] 3D/4D Imaging Mode
[6] Includes imaging of guidance of biopsy (2D/3D/4D)
[7] Includes infertility monitoring of follicle development
[8] Includes urology/prostate
[*] Combined modes are B/M, B/Color M, B/PWD or CWD, B/Color/PWD or CWD, B/Power/PWD.

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Concurrence of CDRH, Office of In Vitro Diagnostics and Radiological Health (OIR)

Prescription User (Per 21 CFR 801.109)

Diagnostic Ultrasound Indications for Use Form

GE Voluson i/e with RSP6-16-RS Transducer

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application *Anatomy/Region of Interest*	Mode of Operation										
	B	M	PW Doppler	CW Doppler	Color Doppler	Color M Doppler	Power Doppler	Combined Modes	Harmonic Imaging	Coded Pulse	Other (Notes)
Ophthalmic											
Fetal / Obstetrics[7]											
Abdominal[1]											
Pediatric	P	P	P		P	P	P	P	P	P	[5,6]
Small Organ[2]	P	P	P		P	P	P	P	P	P	[5,6]
Neonatal Cephalic											
Adult Cephalic											
Cardiac[3]											
Peripheral Vascular	P	P	P		P	P	P	P	P	P	[5,6]
Musculo-skeletal Conventional	P	P	P		P	P	P	P	P	P	[5,6]
Musculo-skeletal Superficial	P	P	P		P	P	P	P	P	P	[5,6]
Other											
Exam Type, Means of Access											
Transesophageal											
Transrectal[8]											
Transvaginal											
Transuretheral											
Intraoperative											
Intraoperative Neurological											
Intravascular											
Laparoscopic											

N = new indication; P = previously cleared by FDA; E = added under Appendix E

Notes: [1] Abdominal includes renal, GYN/Pelvic, Urology
[2] Small organ includes breast, testes, thyroid, salivary gland, lymph nodes, pediatric and neonatal patients
[3] Cardiac is Adult and Pediatric.
[5] 3D/4D Imaging Mode
[6] Includes imaging of guidance of biopsy (2D/3D/4D)
[7] Includes infertility monitoring of follicle development
[8] Includes urology/prostate
[*] Combined modes are B/M, B/Color M, B/PWD or CWD, B/Color/PWD or CWD, B/Power/PWD.

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Concurrence of CDRH, Office of In Vitro Diagnostics and Radiological Health (OIR)

Prescription User (Per 21 CFR 801.109)

Diagnostic Ultrasound Indications for Use Form

GE Voluson i/e with E8C-RS Transducer

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application *Anatomy/Region of Interest*	Mode of Operation										
	B	M	PW Doppler	CW Doppler	Color Doppler	Color M Doppler	Power Doppler	Combined Modes*	Harmonic Imaging	Coded Pulse	Other (Notes)
Ophthalmic											
Fetal / Obstetrics[7]	P	P	P		P	P	P	P	P	P	[6]
Abdominal[1]											
Pediatric											
Small Organ[2]											
Neonatal Cephalic											
Adult Cephalic											
Cardiac[3]											
Peripheral Vascular											
Musculo-skeletal Conventional											
Musculo-skeletal Superficial											
Other											
Exam Type, Means of Access											
Transesophageal											
Transrectal[8]	P	P	P		P	P	P	P	P	P	[6]
Transvaginal	P	P	P		P	P	P	P	P	P	[6]
Transuretheral											
Intraoperative											
Intraoperative Neurological											
Intravascular											
Laparoscopic											

N = new indication; P = previously cleared by FDA; E = added under Appendix E

Notes: [1] Abdominal includes renal, GYN/Pelvic, Urology
[2] Small organ includes breast, testes, thyroid, salivary gland, lymph nodes, pediatric and neonatal patients
[3] Cardiac is Adult and Pediatric.
[5] 3D/4D Imaging Mode
[6] Includes imaging of guidance of biopsy (2D/3D/4D)
[7] Includes infertility monitoring of follicle development
[8] Includes urology/prostate
[*] Combined modes are B/M, B/Color M, B/PWD or CWD, B/Color/PWD or CWD, B/Power/PWD.

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Concurrence of CDRH, Office of In Vitro Diagnostics and Radiological Health (OIR)

Prescription User (Per 21 CFR 801.109)

Diagnostic Ultrasound Indications for Use Form

GE Voluson i/e with 4C-RS Transducer

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application *Anatomy/Region of Interest*	Mode of Operation										
	B	M	PW Doppler	CW Doppler	Color Doppler	Color M Doppler	Power Doppler	Combined Modes[*]	Harmonic Imaging	Coded Pulse	Other [Notes]
Ophthalmic											
Fetal / Obstetrics[7]	P	P	P		P	P	P	P	P	P	[6]
Abdominal[1]	P	P	P		P	P	P	P	P	P	[6]
Pediatric	P	P	P		P	P	P	P	P	P	[6]
Small Organ[2]											
Neonatal Cephalic											
Adult Cephalic											
Cardiac[3]											
Peripheral Vascular	P	P	P		P	P	P	P	P	P	[6]
Musculo-skeletal Conventional											
Musculo-skeletal Superficial											
Other											
Exam Type, Means of Access											
Transesophageal											
Transrectal[8]											
Transvaginal											
Transuretheral											
Intraoperative											
Intraoperative Neurological											
Intravascular											
Laparoscopic											

N = new indication; P = previously cleared by FDA; E = added under Appendix E

Notes: [1] Abdominal includes renal, GYN/Pelvic, Urology
[2] Small organ includes breast, testes, thyroid, salivary gland, lymph nodes, pediatric and neonatal patients
[3] Cardiac is Adult and Pediatric.
[5] 3D/4D Imaging Mode
[6] Includes imaging of guidance of biopsy (2D/3D/4D)
[7] Includes infertility monitoring of follicle development
[8] Includes urology/prostate
[*] Combined modes are B/M, B/Color M, B/PWD or CWD, B/Color/PWD or CWD, B/Power/PWD.

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Concurrence of CDRH, Office of In Vitro Diagnostics and Radiological Health (OIR)

Prescription User (Per 21 CFR 801.109)

Diagnostic Ultrasound Indications for Use Form

GE Voluson i/e with 12L-RS Transducer

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application *Anatomy/Region of Interest*	Mode of Operation										
	B	M	PW Doppler	CW Doppler	Color Doppler	Color M Doppler	Power Doppler	Combined Modes*	Harmonic Imaging	Coded Pulse	Other (Notes)
Ophthalmic											
Fetal / Obstetrics[7]											
Abdominal[1]											
Pediatric	P	P	P		P	P	P	P	P	P	[6]
Small Organ[2]	P	P	P		P	P	P	P	P	P	[6]
Neonatal Cephalic											
Adult Cephalic											
Cardiac[3]											
Peripheral Vascular	P	P	P		P	P	P	P	P	P	[6]
Musculo-skeletal Conventional	P	P	P		P	P	P	P	P	P	[6]
Musculo-skeletal Superficial	P	P	P		P	P	P	P	P	P	[6]
Other											
Exam Type, Means of Access											
Transesophageal											
Transrectal[8]											
Transvaginal											
Transuretheral											
Intraoperative											
Intraoperative Neurological											
Intravascular											
Laparoscopic											

N = new indication; P = previously cleared by FDA; E = added under Appendix E

Notes: [1] Abdominal includes renal, GYN/Pelvic, Urology
[2] Small organ includes breast, testes, thyroid, salivary gland, lymph nodes, pediatric and neonatal patients
[3] Cardiac is Adult and Pediatric.
[5] 3D/4D Imaging Mode
[6] Includes imaging of guidance of biopsy (2D/3D/4D)
[7] Includes infertility monitoring of follicle development
[8] Includes urology/prostate
[*] Combined modes are B/M, B/Color M, B/PWD or CWD, B/Color/PWD or CWD, B/Power/PWD.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostics and Radiological Health (OIR)

Prescription User (Per 21 CFR 801.109)

Diagnostic Ultrasound Indications for Use Form

GE Voluson i/e with RIC5-9W-RS Transducer

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application *Anatomy/Region of Interest*	Mode of Operation										
	B	M	PW Doppler	CW Doppler	Color Doppler	Color M Doppler	Power Doppler	Combined Modes	Harmonic Imaging	Coded Pulse	Other (Notes)
Ophthalmic											
Fetal / Obstetrics[7]	E	E	E		E	E	E	E	E	E	[5,6]
Abdominal[1]											
Pediatric											
Small Organ[2]											
Neonatal Cephalic											
Adult Cephalic											
Cardiac[3]											
Peripheral Vascular											
Musculo-skeletal Conventional											
Musculo-skeletal Superficial											
Other											
Exam Type, Means of Access											
Transesophageal											
Transrectal[8]	E	E	E		E	E	E	E	E	E	[5,6]
Transvaginal	E	E	E		E	E	E	E	E	E	[5,6]
Transuretheral											
Intraoperative											
Intraoperative Neurological											
Intravascular											
Laparoscopic											

N = new indication; P = previously cleared by FDA; E = added under Appendix E (previously cleared Voluson S6/S8 K120741)

Notes: [1] Abdominal includes renal, GYN/Pelvic, Urology
[2] Small organ includes breast, testes, thyroid, salivary gland, lymph nodes, pediatric and neonatal patients
[3] Cardiac is Adult and Pediatric.
[5] 3D/4D Imaging Mode
[6] Includes imaging of guidance of biopsy (2D/3D/4D)
[7] Includes infertility monitoring of follicle development
[8] Includes urology/prostate
[*] Combined modes are B/M, B/Color M, B/PWD or CWD, B/Color/PWD or CWD, B/Power/PWD.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostics and Radiological Health (OIR)

Prescription User (Per 21 CFR 801.109)

Diagnostic Ultrasound Indications for Use Form

GE Voluson i/e with IC5-9W-RS Transducer

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application *Anatomy/Region of Interest*	Mode of Operation										
	B	M	PW Doppler	CW Doppler	Color Doppler	Color M Doppler	Power Doppler	Combined Modes	Harmonic Imaging	Coded Pulse	Other (Notes)
Ophthalmic											
Fetal / Obstetrics[7]	N	N	N		N	N	N	N	N	N	[6]
Abdominal[1]											
Pediatric											
Small Organ[2]											
Neonatal Cephalic											
Adult Cephalic											
Cardiac[3]											
Peripheral Vascular											
Musculo-skeletal Conventional											
Musculo-skeletal Superficial											
Other											
Exam Type, Means of Access											
Transesophageal											
Transrectal[8]	N	N	N		N	N	N	N	N	N	[6]
Transvaginal	N	N	N		N	N	N	N	N	N	[6]
Transuretheral											
Intraoperative											
Intraoperative Neurological											
Intravascular											
Laparoscopic											

N = new indication; P = previously cleared by FDA; E = added under Appendix E

Notes: [1] Abdominal includes renal, GYN/Pelvic, Urology
[2] Small organ includes breast, testes, thyroid, salivary gland, lymph nodes, pediatric and neonatal patients
[3] Cardiac is Adult and Pediatric.
[5] 3D/4D Imaging Mode
[6] Includes imaging of guidance of biopsy (2D/3D/4D)
[7] Includes infertility monitoring of follicle development
[8] Includes urology/prostate
[*] Combined modes are B/M, B/Color M, B/PWD or CWD, B/Color/PWD or CWD, B/Power/PWD.

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Concurrence of CDRH, Office of In Vitro Diagnostics and Radiological Health (OIR)

Prescription User (Per 21 CFR 801.109)

Diagnostic Ultrasound Indications for Use Form

GE Voluson i/e with RAB4-8-RS Transducer

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application *Anatomy/Region of Interest*	Mode of Operation										
	B	M	PW Doppler	CW Doppler	Color Doppler	Color M Doppler	Power Doppler	Combined Modes	Harmonic Imaging	Coded Pulse	Other [Notes]
Ophthalmic											
Fetal / Obstetrics[7]	E	E	E		E	E	E	E	E	E	[5,6]
Abdominal[1]	E	E	E		E	E	E	E	E	E	[5,6]
Pediatric	E	E	E		E	E	E	E	E	E	[5,6]
Small Organ[2]											
Neonatal Cephalic											
Adult Cephalic											
Cardiac[3]											
Peripheral Vascular											
Musculo-skeletal Conventional	E	E	E		E	E	E	E	E	E	[5,6]
Musculo-skeletal Superficial											
Other											
Exam Type, Means of Access											
Transesophageal											
Transrectal[8]											
Transvaginal											
Transuretheral											
Intraoperative											
Intraoperative Neurological											
Intravascular											
Laparoscopic											

N = new indication; P = previously cleared by FDA; E = added under Appendix E (Previously cleared on Voluson S6/S8 (K120741)

Notes: [1] Abdominal includes renal, GYN/Pelvic, Urology
[2] Small organ includes breast, testes, thyroid, salivary gland, lymph nodes, pediatric and neonatal patients
[3] Cardiac is Adult and Pediatric.
[5] 3D/4D Imaging Mode
[6] Includes imaging of guidance of biopsy (2D/3D/4D)
[7] Includes infertility monitoring of follicle development
[8] Includes urology/prostate
[*] Combined modes are B/M, B/Color M, B/PWD or CWD, B/Color/PWD or CWD, B/Power/PWD.

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Concurrence of CDRH, Office of In Vitro Diagnostics and Radiological Health (OIR)

Prescription User (Per 21 CFR 801.109)

Diagnostic Ultrasound Indications for Use Form

GE Voluson i/e with RNA5-9-RS Transducer

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application *Anatomy/Region of Interest*	Mode of Operation										
	B	M	PW Doppler	CW Doppler	Color Doppler	Color M Doppler	Power Doppler	Combined Modes	Harmonic Imaging	Coded Pulse	Other [Notes]
Ophthalmic											
Fetal / Obstetrics[7]	E	E	E	E	E	E	E	E	E	E	[5,6]
Abdominal[1]	E	E	E	E	E	E	E	E	E	E	[5,6]
Pediatric	E	E	E	E	E	E	E	E	E	E	[5,6]
Small Organ[2]	E	E	E	E	E	E	E	E	E	E	[5,6]
Neonatal Cephalic											
Adult Cephalic											
Cardiac[3]	E	E	E	E	E	E	E	E	E	E	[5]
Peripheral Vascular	E	E	E	E	E	E	E	E	E	E	[5,6]
Musculo-skeletal Conventional	E	E	E	E	E	E	E	E	E	E	[5,6]
Musculo-skeletal Superficial											
Other											
Exam Type, Means of Access											
Transesophageal											
Transrectal[8]											
Transvaginal											
Transuretheral											
Intraoperative											
Intraoperative Neurological											
Intravascular											
Laparoscopic											

N = new indication; P = previously cleared by FDA; E = added under Appendix E

Notes: [1] Abdominal includes renal, GYN/Pelvic, Urology
[2] Small organ includes breast, testes, thyroid, salivary gland, lymph nodes, pediatric and neonatal patients
[3] Cardiac is Adult and Pediatric.
[5] 3D/4D Imaging Mode
[6] Includes imaging of guidance of biopsy (2D/3D/4D)
[7] Includes infertility monitoring of follicle development
[8] Includes urology/prostate
[*] Combined modes are B/M, B/Color M, B/PWD or CWD, B/Color/PWD or CWD, B/Power/PWD.

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Concurrence of CDRH, Office of In Vitro Diagnostics and Radiological Health (OIR)

Prescription User (Per 21 CFR 801.109)

Diagnostic Ultrasound Indications for Use Form
GE Voluson i/e with AB2-7-RS Transducer

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application *Anatomy/Region of Interest*	Mode of Operation										
	B	M	PW Doppler	CW Doppler	Color Doppler	Color M Doppler	Power Doppler	Combined Modes	Harmonic Imaging	Coded Pulse	Other (Notes)
Ophthalmic											
Fetal / Obstetrics[7]	E	E	E		E	E	E	E	E	E	[6]
Abdominal[1]	E	E	E		E	E	E	E	E	E	[6]
Pediatric	E	E	E		E	E	E	E	E	E	[6]
Small Organ[2]											
Neonatal Cephalic											
Adult Cephalic											
Cardiac[3]											
Peripheral Vascular											
Musculo-skeletal Conventional											
Musculo-skeletal Superficial											
Other	E	E	E		E	E	E	E	E	E	[6]
Exam Type, Means of Access											
Transesophageal											
Transrectal[8]											
Transvaginal											
Transurethral											
Intraoperative											
Intraoperative Neurological											
Intravascular											
Laparoscopic											

N = new indication; P = previously cleared by FDA; E = added under Appendix E (Previously cleared on Voluson S6/S8 (K120741)

Notes: [1] Abdominal includes renal, GYN/Pelvic, Urology
[2] Small organ includes breast, testes, thyroid, salivary gland, lymph nodes, pediatric and neonatal patients
[3] Cardiac is Adult and Pediatric.
[5] 3D/4D Imaging Mode
[6] Includes imaging of guidance of biopsy (2D/3D/4D)
[7] Includes infertility monitoring of follicle development
[8] Includes urology/prostate
[*] Combined modes are B/M, B/Color M, B/PWD or CWD, B/Color/PWD or CWD, B/Power/PWD.

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Concurrence of CDRH, Office of In Vitro Diagnostics and Radiological Health (OIR)

Prescription User (Per 21 CFR 801.109)

Diagnostic Ultrasound Indications for Use Form

GE Voluson I/e with 9L-RS Transducer

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application / *Anatomy/Region of Interest*	Mode of Operation										
	B	M	PW Doppler	CW Doppler	Color Doppler	Color M Doppler	Power Doppler	Combined Modes*	Harmonic Imaging	Coded Pulse	Other (Notes)
Ophthalmic											
Fetal / Obstetrics[7]	E	E	E		E	E	E	E	E	E	
Abdominal[1]	E	E	E		E	E	E	E	E	E	
Pediatric	E	E	E		E	E	E	E	E	E	
Small Organ[2]	E	E	E		E	E	E	E	E	E	
Neonatal Cephalic											
Adult Cephalic											
Cardiac[3]											
Peripheral Vascular	E	E	E		E	E	E	E	E	E	
Musculo-skeletal Conventional	E	E	E		E	E	E	E	E	E	
Musculo-skeletal Superficial	E	E	E		E	E	E	E	E	E	
Other											
Exam Type, Means of Access											
Transesophageal											
Transrectal[8]											
Transvaginal											
Transurethral											
Intraoperative											
Intraoperative Neurological											
Intravascular											
Laparoscopic											

N = new indication; P = previously cleared by FDA; E = added under Appendix E (Previously cleared on Voluson S6/S8 (K120741)

Notes: [1] Abdominal includes renal, GYN/Pelvic, Urology
[2] Small organ includes breast, testes, thyroid, salivary gland, lymph nodes, pediatric and neonatal patients
[3] Cardiac is Adult and Pediatric.
[5] 3D/4D Imaging Mode
[6] Includes imaging of guidance of biopsy (2D/3D/4D)
[7] Includes infertility monitoring of follicle development
[8] Includes urology/prostate
[*] Combined modes are B/M, B/Color M, B/PWD or CWD, B/Color/PWD or CWD, B/Power/PWD.

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Concurrence of CDRH, Office of In Vitro Diagnostics and Radiological Health (OIR)

Prescription User (Per 21 CFR 801.109)

Diagnostic Ultrasound Indications for Use Form

GE Voluson i/e with SP10-16-RS Transducer

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application *Anatomy/Region of Interest*	Mode of Operation										
	B	M	PW Doppler	CW Doppler	Color Doppler	Color M Doppler	Power Doppler	Combined Modes*	Harmonic Imaging	Coded Pulse	Other (Notes)
Ophthalmic											
Fetal / Obstetrics[7]											
Abdominal[1]											
Pediatric	E	E	E		E	E	E	E	E	E	[6]
Small Organ[2]	E	E	E		E	E	E	E	E	E	
Neonatal Cephalic											
Adult Cephalic											
Cardiac[3]											
Peripheral Vascular	E	E	E		E	E	E	E	E	E	[6]
Musculo-skeletal Conventional											
Musculo-skeletal Superficial	E	E	E		E	E	E	E	E	E	[6]
Other											
Exam Type, Means of Access											
Transesophageal											
Transrectal[8]											
Transvaginal											
Transuretheral											
Intraoperative						✓					
Intraoperative Neurological											
Intravascular											
Laparoscopic											

N = new indication; P = previously cleared by FDA; E = added under Appendix E

Notes: [1] Abdominal includes renal, GYN/Pelvic, Urology
[2] Small organ includes breast, testes, thyroid, salivary gland, lymph nodes, pediatric and neonatal patients
[3] Cardiac is Adult and Pediatric.
[5] 3D/4D Imaging Mode
[6] Includes imaging of guidance of biopsy (2D/3D/4D)
[7] Includes infertility monitoring of follicle development
[8] Includes urology/prostate
[*] Combined modes are B/M, B/Color M, B/PWD or CWD, B/Color/PWD or CWD, B/Power/PWD.

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Concurrence of CDRH, Office of In Vitro Diagnostics and Radiological Health (OIR)

Prescription User (Per 21 CFR 801.109)

Diagnostic Ultrasound Indications for Use Form

GE Voluson i/e with RAB2-6-RS Transducer

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application *Anatomy/Region of Interest*	Mode of Operation										
	B	M	PW Doppler	CW Doppler	Color Doppler	Color M Doppler	Power Doppler	Combined Modes	Harmonic Imaging	Coded Pulse	Other (Notes)
Ophthalmic											
Fetal / Obstetrics[7]	P*	P*	P*		P*	P*	P*	P*	P*	P*	[5,6]
Abdominal[1]	P*	P*	P*		P*	P*	P*	P*	P*	P*	[5,6]
Pediatric	P*	P*	P*		P*	P*	P*	P*	P*	P*	[5,6]
Small Organ[2]											
Neonatal Cephalic											
Adult Cephalic											
Cardiac[3]											
Peripheral Vascular											
Musculo-skeletal Conventional	P*	P*	P*		P*	P*	P*	P*	P*	P*	[5,6]
Musculo-skeletal Superficial											
Other											
Exam Type, Means of Access											
Transesophageal											
Transrectal[8]											
Transvaginal											
Transuretheral											
Intraoperative											
Intraoperative Neurological											
Intravascular											
Laparoscopic											

N = new indication; P = previously cleared by FDA (K122387); E = added under Appendix E

Notes: [1] Abdominal includes renal, GYN/Pelvic, Urology
[2] Small organ includes breast, testes, thyroid, salivary gland, lymph nodes, pediatric and neonatal patients
[3] Cardiac is Adult and Pediatric.
[5] 3D/4D Imaging Mode
[6] Includes imaging of guidance of biopsy (2D/3D/4D)
[7] Includes infertility monitoring of follicle development
[8] Includes urology/prostate
[*] Combined modes are B/M, B/Color M, B/PWD or CWD, B/Color/PWD or CWD, B/Power/PWD.

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Concurrence of CDRH, Office of In Vitro Diagnostics and Radiological Health (OIR)

Prescription User (Per 21 CFR 801.109)

Diagnostic Ultrasound Indications for Use Form
GE Voluson i/e with 8C-RS Transducer

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application *Anatomy/Region of Interest*	Mode of Operation										
	B	M	PW Doppler	CW Doppler	Color Doppler	Color M Doppler	Power Doppler	Combined Modes	Harmonic Imaging	Coded Pulse	Other (Notes)
Ophthalmic											
Fetal / Obstetrics[1]	P*	P*	P*		P*	P*	P*	P*	P*	P*	
Abdominal[1]	P*	P*	P*		P*	P*	P*	P*	P*	P*	
Pediatric	P*	P*	P*		P*	P*	P*	P*	P*	P*	
Small Organ[2]	P*	P*	P*		P*	P*	P*	P*	P*	P*	
Neonatal Cephalic											
Adult Cephalic											
Cardiac[3]	P*	P*	P*		P*	P*	P*	P*	P*	P*	
Peripheral Vascular	P*	P*	P*		P*	P*	P*	P*	P*	P*	
Musculo-skeletal Conventional	P*	P*	P*		P*	P*	P*	P*	P*	P*	
Musculo-skeletal Superficial	P*	P*	P*		P*	P*	P*	P*	P*	P*	
Other											
Exam Type, Means of Access											
Transesophageal											
Transrectal[3]											
Transvaginal											
Transuretheral											
Intraoperative											
Intraoperative Neurological											
Intravascular											
Laparoscopic											

N = new indication; P *= previously cleared by FDA K120741; E = added under Appendix E

Notes: [1] Abdominal includes renal, GYN/Pelvic, Urology
[2] Small organ includes breast, testes, thyroid, salivary gland, lymph nodes, pediatric and neonatal patients
[3] Cardiac is Adult and Pediatric.
[*] Combined modes are B/M, B/Color M, B/PWD or CWD, B/Color/PWD or CWD, B/Power/PWD.

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Concurrence of CDRH, Office of In Vitro Diagnostics and Radiological Health (OIR)

Prescription User (Per 21 CFR 801.109)

(Division Sign-Off)
Division of Radiological Devices
Office of *In Vitro* Diagnostic Device Evaluation and Safety
510(k) Number K131937